DETAILED ACTION

This application is a 371 (national stage application) of PCT/GB05/00024.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2012, has been entered.

Receipt of Amendments/Remarks filed on January 30, 2012, is acknowledged. In response to final Office Action dated August 16, 2011, applicant amended claims 65, 72, & 74, canceled claims 66-71, 73, 77-92, 94-96, 98-103, 105, 107, & 109-113, and added no new claims. Claims 65, 72, 74, & 75, are pending. Claims 65, 72, 74, & 75, are under examination.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. All new rejections applied have been necessitated by applicant's amendment to the claims. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

> art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 65 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 65 recites the range "from 0.002 to 0.010%" for fipronil; however, there is no support in the specification or claims as originally filed for the upper limit of this range (as either 0.010% or 100 ppm). Therefore, it is the Examiner's position that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of filing of the instant application.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 65, 72, 74, & 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liers et al. (Medical and Veterinary Entomology, vol. 15, p299-303, cited by applicants on IDS) in view of the Petterino et al. (Veterinary and Human Toxicology, volume 43 issue 6, p353-360) and as evidenced by Rowe et al. (The Journal of Hygiene, Vol. 81, No. 2 (Oct., 1978), pp. 197-201).

Applicant claims

Applicant claims a rodenticidal composition consisting essentially of fipronil, a second generation rodenticide, and a feeding stimulant. For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” (See MPEP 2111.03)

Determination of the scope and content of the prior art (MPEP 2141.01)

Liers et al. teach, as a whole, a composition containing fipronil, bromadiolone (a second generation rodenticide) and a feeding stimulant as well as methods of controlling fleas and the rats they inhabit.

Claim 65 & 72: Liers et al. teach bait comprising fipronil, bromadiolone (a rodenticide) and crushed wheat (a cereal grain and feeding stimulant) (Materials and Methods section, especially page 300, first full paragraph). Liers et al. teach fipronil concentrations of 0.0005 and 0.005% and a rodenticide concentration of 0.005% with the remainder being feeding stimulant (Materials and Methods section, especially page 300, first 2 full paragraphs and table 2).

Claims 74: Liers et al. teach increasing the palatability of the bait by possibly adding rice (a cereal grain, hence an attractant) to the bait (p 303, last full paragraph).

Claims 75: Liers et al. teach using a solvent (acetone or propylene glycol) in the composition (p 300, third full paragraph and table 2).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the teachings Liers et al. and the instant claims is that Liers et al. uses bromadiolone as the rodenticide, whereas the claims select the rodenticide from the group consisting of brodifacoum, difethialone, and mixtures thereof. This deficiency in the teachings of Liers et al. is cured by the teachings of Petterino et al.

Petterino et al. teach bromadiolone, brodifacoum, difethialone, and flocoumafen are all useful as second-generation, anticoagulant rodenticides (page 353, 3rd paragraph). Petterino et al. also teach that bromadiolone has a higher LD_{50} against rodents (less effective as a rodenticide) than brodifacoum, difethialone, and flocoumafen (page 355-357, tables 4, 5 ,7, & 8).

Further Rowe et al. establish that 0.005% brodifacoum in a feeding stimulant is an amount known in the art to be effective against rodents (specifically house mice) (abstract).

Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute brodifacoum, or difethialone for bromadiolone in the bait and method of Liers et al. as well as using the bait because brodifacoum and difethialone are art-recognized as more effective rodenticides than bromadiolone. The ordinary artisan would have been motivated to use brodifacoum, or difethialone instead of bromadiolone because the Petterino et al. teach that brodifacoum and difethialone are more potent rodenticides of the same type.

All the critical elements of the instant claims are disclosed. The amounts and proportions of each ingredient are result-effective parameters chosen to obtain the desired effects especially when the art guides the artisan to use the agents within the ranges instantly claimed thus providing sufficient specificity. It would be obvious to vary amounts of the ingredients to optimize the effect desired, depending upon the particular

host species and application method of interest, reduction of toxicity, cost minimization, enhanced, and prolonged, or synergistic effects. Applicant has not provided any objective evidence of criticality, non-obvious or unexpected results that the administration of the particular ingredients' or concentrations provides any greater or different level of prior art expectation as claimed (in fact, applicant's examples all contain 50 ppm brodifacoum), and the use of ingredient for the functionality for which they are known to be used is not basis for patentability. The instant invention provides well-known old art-recognized compounds, with well-known art-recognized effects, applied by well-known art-recognized methods to achieve improved control as is well-known in the art.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in using brodifacoum or difethialone as a rodenticide in the compositions and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

6. Applicant's arguments filed January 30, 2012, have been fully considered but they are not persuasive.

Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

The expected result remains the same; a combination rodenticide/fipronil composition is made in the absence of evidence to the contrary. No unexpected results have been presented and the criticality of the amount of each component has not been shown. Applicant's arguments are not persuasive, and the rejection under 35 U.S.C. §103(a) is maintained. The examiner cannot identify allowable subject matter and applicant is directed to MPEP 707.07(d), second and third paragraphs, for interpreting the examiner's stated ground of rejection.

Conclusion

Claims 65, 72, 74, & 75 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571)270-5870. The examiner can normally be reached on Mon-Fri 7:30-3:30 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Kwon can be reached on (571)272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. R. L./
Examiner, Art Unit 1613

crl

/Ernst V Arnold/
Primary Examiner, Art Unit 1613